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Companywide	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 01/27/03
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Manual: 13A-Quality and Requirements Management Program Documents

Change Number: 96536

1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for the company *quality assurance* (QA; see def.) program. See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to company organizations that prescribe, perform, or verify activities, including those having responsibility for planning and scheduling.

3. RESPONSIBILITIES

3.1 Bechtel, BWXT Idaho, LLC (BBWI) President and Laboratory Director

The BBWI President, General Manager and Laboratory Director is responsible for the scoping, planning, implementation, and maintenance of the overall QA program. Details of the President, General Manager and Laboratory Director's responsibilities are provided in PRD-5070, 1.1 Organization.

3.2 Environment, Safety, Health, and Quality Assurance (ESH&QA) General Manager

The Environment, Safety, Health, and Quality Assurance (ESH&QA) General Manager is responsible for defining policy and management direction for the establishment and implementation of the company QA program. The ESH&QA General Manager is also responsible for the *Price-Anderson Amendments Act of 1998* (see def.) compliance program including INEEL inputs to the DOE Headquarters Noncompliance Tracking System.

Further details of the ESH&QA General Manager's responsibilities are provided in PRD-5070, 1.1 Organization.

3.3 Quality Assurance Director

The Quality Assurance Director is responsible for directing, developing and maintaining the company QA program, and assuring and verifying its implementation. Additional details of the Quality Assurance Director's responsibilities are provided in PRD-5070, 1.1 Organization.

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The Quality Assurance Director is responsible for providing quality engineering, inspection, calibration and procurement quality services. This includes, but is not limited to:

- A. Managing technical aspects of the company's QA program.
- B. Providing technical assistance/guidance to directors, managers, and staff in identifying QA requirements.
- C. Resolving with line management those conditions not in compliance with QA program requirements to ensure that the conditions are corrected in an appropriate and timely manner.
- D. Serving as Chair of the Site Quality Council.
- E. Providing technical direction of QA *training* (see def.).
- F. Preparing, implementing, and maintaining the company QA PRDs.
- G. Implementing established quality policy and defining program direction in compliance with QA program requirements.
- H. Developing, coordinating, and maintaining company QA *procedures* (see def.) that establish requirements and *processes* (see def.) for implementing the QA program.
- I. Supporting the company's goal of operational excellence and integrated safety management.
- J. Managing the company's process for controlling nonconforming items.

3.4 Performance Assurance Director

The Performance Assurance Director is responsible for:

- A. Maintaining and directing activities for the independent oversight, compliance assurance, issues management, and performance measurement programs.
- B. Providing for *indoctrination* (see def.) and training of *audit* (see def.) personnel.
- C. Establishing and maintaining a *qualification* (see def.) and certification program for *auditor/lead auditors* (see defs.)

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- D. Ensuring preparation and execution of an annual independent audit schedule.
- E. Reporting the results of independent audits to the area manager assessed.
- F. Developing and maintaining documents that establish and implement performance assurance requirements, activities, and processes.
- G. Assisting company management in implementation of performance assurance processes.
- H. Managing the corrective action system for ESH&QA issues, including reportable events or conditions, adverse and significant deficiencies, safety concerns, and other issues.
- I. Administering the Issues Communication and Resolution Environment (ICARE) for electronic tracking of issues and corrective actions.
- J. Managing the Lessons Learned program for identification, evaluation, and tracking of noteworthy practices and conditions requiring corrective or preventive actions.
- K. Administering the Performance Reporting and Analysis program for establishing, analyzing, and reporting ESH&QA performance objectives, measures, and commitments.
- L. Evaluating ESH&QA performance and reporting the evaluation results to Senior Management.
- M. Managing the Integrated Assessment program including the integrated assessment schedule and database and point-of-contact for assessments/audits/evaluations by external agencies.

3.5 Supply Chain Management and Contracts Director

The Supply Chain Management and Contracts Director is responsible for the supply and contracting process at the INEEL. A summary of the Director's responsibilities is provided in PRD-5070, 1.1 Organization.

3.6 Procurement and Supplier Quality Manager

The Procurement and Supplier Quality (PSQ) Manager is responsible for establishing and maintaining a centralized QA functional organization and being the single point of contact for all matters associated with the procurement process and *supplier* (see def.) quality. The PSQ manager is responsible for

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integrating the QA PRD with the companywide procurement process. Other responsibilities include:

- A. Interfacing with INEEL management, DOE counterparts, and other personnel to ensure respective programs are implemented and executed, site-wide issues are resolved, and continuous improvements are made. Establishing, maintaining, and implementing companywide procurement quality processes and procedures that comply with all applicable QA PRD requirements as well as best management and commercial practices for procurement.
- B. Maintaining supplier qualification/*certification* (see def.), quality engineering, and product *verification* (see def.) services as required by established procedures.
- C. Providing additional support services to the Supply Chain Management and Contracts (SCM&C) functional area as directed.
- D. Integrating quality–assuring functions into the company business systems for procurement and the procurement process.
- E. Developing, analyzing, and reporting process *data* (see def.), as required, to monitor performance and promote procurement process improvement.
- F. Functioning as the liaison between SCM&C and QA, assuring integration of changing or emerging requirements for QA into the procurement process.
- G. Providing expertise and consulting services to SCM&C regarding matters of QA policy and requirements.

3.7 Quality Assurance Operations Manager

The Quality Assurance Operations Manager is responsible for ensuring that the company's calibration program and *calibration* (see def.) activities comply with the requirements of the QA program and all applicable codes and standards. The Quality Assurance Operations manager is also responsible for maintaining the QA program documents, the QA training program, special projects and self-assessment program. Duties include, but are not limited to:

- A. Providing high quality calibration standards and services to all company organizations.

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- B. Providing day-to-day leadership and guidance for the sitewide calibration program. This includes providing technical expertise, assistance, and advice to company management and DOE operations.
- C. Managing activities of the Standard and Calibration Laboratories.
- D. Providing training and qualification for calibration personnel.
- E. Administering the site-wide Test Equipment Pool.
- F. Performing *surveillance* (see def.) of calibration activities to ensure compliance to requirements.
- G. Providing guidance, coordination, and assistance to facilities in establishing and implementing quality program requirements.
- H. Managing the QA Program documents so they are correct.
- I. Establishing and maintaining the program for qualification of quality engineers.
- J. Performing activities to address special projects that are identified.
- K. Overseeing the QA self-assessment program.

3.8 Environmental Operations and Nuclear Operations Quality Assurance Managers

The Environmental Operations and Nuclear Operations Quality Assurance Managers are responsible for:

- A. Providing (matrixing) qualified quality personnel (quality engineers and *inspectors* [see def.]) to support the line organization's implementation and maintenance of the QA program.
- B. Interfacing with facility and DOE-ID personnel to facilitate problem resolution, achievement of quality objectives, and responsiveness to customer needs.
- C. Conducting surveillance of line organizations to verify implementation of the QA program.
- D. Providing nondestructive examination and inspection services to line organizations.

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- E. Establishing and maintaining the program for qualification and certification of nondestructive examiners and inspectors.

3.9 Cognizant Quality Engineer

The *Cognizant Quality Engineer* (see def.) is responsible for providing QA support, which includes, but is not limited to:

- A. Reviewing QA implementing procedures and selected program documents and operating procedures prepared within the performing organization for quality related activities.
- B. Assisting the line organization in identifying and resolving quality issues.
- C. Preparing internal implementing procedures.
- D. Assisting the line organization in identifying and solving problems.
- E. Reviewing and approving quality *procurement documents* (see def.).
- F. Reviewing *nonconformance* (see def.) documentation.
- G. Performing and documenting independent QA inspections and tests where applicable.
- H. Evaluating selected QA data, and reporting results to appropriate levels of management.
- I. Identifying and documenting necessary *witness* and *hold points* (see def.) through inspection planning and/or procedure review.
- J. Providing analytical support for production processes as related to the QA discipline.
- K. Participating in the Unusual Occurrence Report (UOR) process as requested.
- L. Issuing *stop work orders* (see def.) when *conditions adverse to quality* (see def.) require immediate corrective action.
- M. Assessing the supported organization's QA program and identifying management problems that hinder the organization from achieving its objectives.

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3.10 Cognizant Quality Inspectors

Cognizant Quality Inspectors are responsible for:

- A. Providing inspection and nondestructive examination (NDE) support to programs, projects, facilities, and support organizations.
- B. Interfacing with quality engineers and others in the preparing inspection plans and procedures.
- C. Performing inspection, NDE, and test verifications in accordance with approved written plans and procedures.
- D. Documenting the results of inspections, examinations, and tests on *items* (see def.) that have been submitted for quality verification.
- E. Initiating a nonconformance report on items that do not pass inspection, test, or examination criteria.
- F. Statusing nonconforming items to prevent their inadvertent use or installation.
- G. Maintaining personal qualifications current in inspection and NDE disciplines.

3.11 Line Organization Managers

Line Organization (see def.) Managers are responsible for:

- A. Designating individuals or organizations responsible for implementing the requirements of the QA PRDs (e.g., *technical support organization* [see def.]) and defining the interfaces with *external organizations* [see def.].
- B. Identifying the responsibilities and authorities of those organizations and management.
- C. Ensuring implementation of the QA program within their organizations.
- D. Resolving quality deficiencies and implementing timely *corrective action* (see def.).

4. REQUIREMENTS**4.1 Companywide Application**

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The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 Basic

- 4.1.1.1 A documented quality assurance program shall be planned, implemented, and maintained in accordance with NQA-1-1997, Part 1. The program shall identify the activities and items to which it applies. *[NQA-1-1997, Requirement 2, 100(a) 1s and 100(a) 2s; DOE-ID Order 414.A, Attachment 2, 3.a.(2).1s]*
- 4.1.1.2 The quality assurance program shall comply with the requirements of 10 CFR 830.120, DOE Order 414.1, and any other applicable regulations, commitments, and permit conditions, including program specific requirements imposed by other DOE elements via the contract. *[DOE-ID Order 414.A, Attachment 2, 3.a.(1) and 3.a.(3); DOE Order 414.1A, Attachment 1, 1.a.(3)(d)]*
- 4.1.1.3 ASME NQA-1-1997 must be used to the extent that it does not contradict or alter the regulatory requirements, license commitments, or permit conditions imposed by other regulatory agencies. *[DOE-ID Order 414.A, Attachment 2, 3.a.(2) 2s]*
- 4.1.1.4 Wherever applicable, appropriate standards shall be identified, documented, and used (consistent with the National Technology Transfer and Advancement Act, P.L. 104-113, and Office of Management and Budget Circular A-119) to develop and implement the quality assurance program. *[DOE Order 414.1A, Attachment 1, 1.a.(4)]*
- 4.1.1.5 Some work is subject to regulation by quality assurance requirements from the Nuclear Regulatory Commission (NRC), an NRC Agreement State, the Environmental protection Agency, DOE (10 CFR 830.120), or other government agencies. DOE O 414.1A requirements shall be applied to those portions of the work that are not so regulated. *[DOE Order 414.1A, Attachment 1, 1.c.(1)]*
- 4.1.1.6 Spent Fuel Programs and other activities performed by BBWI subject to the *Office of Civilian Radioactive Waste Management* (see def.) Requirement, DOE/RW-0333P, shall meet those requirements as well as those of DOE Order 414.1A. *[DOE Order 414.1A, Attachment 1, 1.c.(2)]*
- 4.1.1.7 The quality assurance program shall be established at the earliest time consistent with the schedule for accomplishment of activities. *[NQA-1-1997, Requirement 2, 100(a) 5s]*

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- 4.1.1.8 The quality assurance program must be operated as an integral, but visible, part of how the company conducts its business. [DOE-ID Order 414.A, Attachment 2, 3.b]
- 4.1.1.9 Subcontractors and suppliers to whom the quality assurance criteria will be applied shall be determined and the quality assurance program must describe how the quality assurance criteria will be applied to those entities. [DOE Order 414.1A, Attachment 1, 1.a.(5) and Attachment 1, 1.a.(3)(f)]
- 4.1.1.10 The program shall include monitoring activities against *acceptance criteria* (see def.) in a manner sufficient to provide assurance that activities affecting quality are performed satisfactorily. [NQA-1-1997, Requirement 2, 100(a)4s]
- 4.1.1.11 Requirement Deleted.
- 4.1.1.12 The quality assurance program shall implement *suspect/counterfeit item* (see def.) controls to the extent commensurate with the risks posed and ensure that the controls contribute to a hazard-free work place in accordance with DOE 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, Attachment 2, Contractor Requirements Documents. [DOE Order 440.1A, Attachment 2, 22]
- 4.1.1.13 The quality assurance criteria shall be implemented in a manner sufficient to achieve adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards. [DOE Order 414.1A, Attachment 1, 1.a.2]
- 4.1.1.14 The quality assurance program must integrate the quality assurance criteria with the safety management system (SMS) description developed for 48 Code of Federal Regulations (CFR) 970.5204-2, or describe how the quality assurance criteria will be applied to the SMS. [DOE Order 414.1A, Attachment 1, 1.a.(3)(e)]
- 4.1.1.15 The program shall provide control over *activities affecting quality* (see def.) to an extent consistent with their importance. [NQA-1-1997, Requirement 2, 100(a) 3s]
- 4.1.1.16 The quality assurance program shall use a *graded approach* (see def.) to apply the quality assurance criteria and describe how the approach will be applied. [DOE Order 414.1A, Attachment 1, 1.a.(3)(b) and 1.a.(3)(c)]

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- 4.1.1.17 A graded approach based upon risk shall be used in categorizing *systems, structures, and components* (see def.) for applying QA controls, as referenced in Subsection 4.1.2. [*Company Imposed Requirement*]
- 4.1.1.18 Cost reduction and efficiency improvement efforts shall be fully compatible with quality performance and improvement of quality. [*DOE Order 414.A, Attachment 2, 3.c*]
- 4.1.1.19 Organizations shall establish implementing documents applicable to their scope of work that translate the quality assurance requirements into work processes. [*DOE/RW-0333P 2.2.1.B*]
- 4.1.1.20 The organization shall establish and implement processes to detect and correct quality problems. [*NQA-1-1997, Requirement 2, 100(a) 9s*]
- 4.1.1.21 When more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clear, defined, and documented. [*NQA-1-1997, Requirement 1, 300 1s; DOE/RW-0333P 2.2.1.B 3*]
- 4.1.1.22 The external interfaces between organizations and internal interfaces between organizational units, and changes thereto, shall be documented. [*NQA-1-1997, Requirement 1, 300 2s; DOE/RW-0333P 2.2.1.B.3*]
- 4.1.1.23 The quality assurance *guidance* (see def.) provided by the latest revision of the DOE G 414.1-1 and DOE G 414.1-2 must be considered in developing and implementing the quality assurance program. [*DOE Order 414.1A, Attachment 1, 1.d*]
- 4.1.1.24 The quality assurance program must be implemented as approved and modified by DOE. Changes may be made to an approved quality assurance program. However, changes made over the previous year must be submitted annually to DOE for review and *approval* (see def.). The submittal must identify the changes, the reason for the changes, and the basis for concluding that the revised quality assurance program continues to satisfy the requirements of DOE Order 414.1A, Attachment 1. [*DOE Order 414.1A, Attachment 1, 1.a.(7), 1.(b), 1.b.(1) and 1.b.(2)*]
- 4.1.1.25 Quality program plans shall be written when there is a need to deviate from the company's base quality assurance program or to address unique customer requirements for a specific program or project. [*Company Imposed Requirement*]

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- 4.1.1.26 Quality assurance project plans shall be written to address how Environmental Protection Agency requirements are applied to company operations. *[Summary of EPA and other requirements sources]*

4.1.2 Applying Controls

- 4.1.2.1 Quality assurance controls (grading) shall be applied to the degree commensurate with the *[DOE/RW-0333P 2.2.4]*:
- A. Function or end use of the item. *[DOE/RW-0333P 2.2.4.A]*
 - B. Consequence of failure (risk) of the item.
[DOE/RW-0333P 2.2.4.B]
 - C. Importance of the data being collected or analyzed.
[DOE/RW-0333P 2.2.4.C]
 - D. Complexity of design or fabrication of the item or design or implementation of the activity. *[DOE/RW-0333P 2.2.4.D]*
 - E. Reliability of the process. *[DOE/RW-0333P 2.2.4.E]*
 - F. Reproducibility of the results. *[DOE/RW-0333P 2.2.4.F]*
 - G. Uniqueness of the item or degree of standardization.
[DOE/RW-0333P 2.2.4.G]
 - H. History of the item or service quality. *[DOE/RW-0333P 2.2.4.H]*
 - I. Necessity of special controls or processes.
[DOE/RW-0333P 2.2.4.I]
 - J. Degree to which functional compliance can be demonstrated through inspection or test. *[DOE/RW-0333P 2.2.4.J]*
 - K. The relative importance to safety, safeguards and security; the magnitude of any hazard involved; the life-cycle stage of a facility; the programmatic mission of a facility; the peculiar characteristics of a facility; and any other relevant factors.
[DOE O 414.1A 7.b]

4.1.3 Planning Work

- 4.1.3.1 Planning shall be documented to ensure work is accomplished under suitably controlled conditions. *[DOE/RW-0333P 2.2.5.1s; NQA-1-1997, Requirement 2, 100(a) 6s]*

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4.1.3.2 Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. [NQA-1-1997, Requirement 2, 100(a) 7s]

4.1.3.3 The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items, and for verification of that quality. [NQA-1-1997, Requirement 2, 100(a) 8s]

4.1.4 Personnel Qualification

NOTE: *Personnel training and qualification requirements are addressed in PRD-5072, 2.2 Personnel Training and Qualification.*

4.1.5 QA Program Information Management

4.1.5.1 Relevant organization management shall, on a continuing basis, be apprised of the status, adequacy, and compliance aspects of the QA program. [DOE/RW-0333P 2.2.11.1s]

4.1.5.2 Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trending reports, and *management assessment* (see def.) reports, [DOE/RW-0333P 2.2.11.2s]

4.1.6 Records

4.1.6.1 All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

4.2 Specific Requirements for DOE/RW-0333P QARD Revision 10 Applications

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the Spent Nuclear Fuel Program.

4.2.1 Quality Assurance Program Documents

4.2.1.1 *Affected organizations* (see def.) shall issue a policy statement signed by senior line management directing mandatory compliance with this quality assurance program. [DOE/RW-0333P 2.2.1.A]

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- 4.2.1.2 The following requirements apply to implementing documents
[DOE/RW-0333P 2.2.1.B.2s]:
- A. Each affected organization shall establish a structured system of implementing documents that provides for top down implementation of the Quality Assurance Requirements Description (QARD) or, if stipulated in procurement documents, shall work to the implementing documents of another affected organization. [DOE/RW-0333P 2.2.1.B.1]
 - B. The system shall accommodate the size and location(s) of the organization, the organizational structure, and the nature of the work such that management processes will be carried out efficiently and effectively. [DOE/RW-0333P 2.2.1.B.2]
 - C. Each affected organization shall review revisions to the QARD and incorporate changes into their implementing documents, as appropriate. [DOE/RW-0333P 2.2.1.B.4]
 - D. Each affected organization shall complete a QARD requirements matrix for the portion of the QARD which they are implementing. [DOE/RW-0333P 2.2.1.C]
 - E. The matrix shall identify [DOW/RW-0333P 2.2.1.C.1]:
 - 1. Where the QARD requirements are directly addressed [DOE/RW-0333P 2.2.1.C.1a]
 - 2. Where QARD requirements are not applicable based on scope of work [DOE/RW-0333P 2.2.1.C.1.b]
 - 3. Where exceptions to QARD requirements have been taken including justification. [DOE/RW-0333P 2.2.1.C.1.c]
- 4.2.1.3 Initial QARD requirements matrices shall be reviewed by the Office of Quality Assurance in accordance with QARD Subsection 2.2.10, Document Review. [DOE/RW-0333P 2.2.1.C.2]
- 4.2.1.4 As changes are made to implementing documents each affected organization shall ensure that respective QARD requirements matrices are revised if necessary. [DOE/RW-0333P 2.2.1.C.3]

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- 4.2.1.5 Changes to QARD requirements matrices shall be reviewed by the quality assurance organization in accordance with QARD Subsection 2.2.10, Document Review. [DOE/RW-0333P 2.2.1.C.4]

4.2.2 Classifying Items

- 4.2.2.1 The quality assurance program shall apply to the following, which shall be included on a *Q-List* (see def.) [DOE/RW-0333P 2.2.2.A]:
- A. Items important to public radiological safety as described in 10 Code of Federal Regulations (CFR) Parts 60, 71, and 72. [DOE/RW-0333P 2.2.2.A.1]
 - B. Items and natural barriers important to waste isolation as described in 10 CFR Part 60. [DOE/RW-0333P 2.2.2.A.2]
 - C. Items required for the control and management of site-generated radioactive waste other than spent fuel and high-level waste. [DOE/RW-0333P 2.2.1.A.3]
 - D. Items required for the protection of items important to safety and waste isolation from the hazards of fire. [DOE/RW-0333P 2.2.2.A.4]
 - E. Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function. [DOE/RW-0333P 2.2.2.A.5]
 - F. Items required to control occupational radiological exposure. [DOE/RW-0333P 2.2.2.A.6]
 - G. Items required for physical protection as defined by 10 CFR Part 73. [DOE/RW-0333P 2.2.2.B]

4.2.3 Controlling Activities

- 4.2.3.1 The quality assurance program shall apply to *site characterization* (see def.) data and samples. [DOE/RW-0333P 2.2.3.A]

NOTE: *Site characterization for the purpose of quality assurance program applicability includes activities related to sample collection and the collection and analysis of data. [DOE/RW-0333P 2.2.3.A Note]*

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- 4.2.3.2 The quality assurance program shall apply to activities related to the items in Section 4.2.2 (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, *testing* (see def.), operation, maintenance, *repair* (see def.), modification, and decontamination). [DOE/RW-0333P 2.2.3.B]
- 4.2.3.3 The quality assurance program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility. [DOE/RW-0333P 2.2.3.C]
- 4.2.3.4 The quality assurance program shall apply to activities related to the high-level waste form development through qualification, production, and *acceptance* (see def.). [DOE/RW-0333P 2.2.3.D]
- 4.2.3.5 The quality assurance program shall apply to activities associated with characterization of U.S. Department of Energy (DOE) spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel. [DOE/RW-0333P 2.2.3.E]

4.2.4 Planning Work

- 4.2.4.1 Planning elements shall include, as appropriate [DOE/RW-0333P 2.2.5.2s]:
- A. Definition of the work scope, objectives, and a listing of the primary tasks involved. [DOE/RW-0333P 2.2.5.A]
 - B. Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work. [DOE/RW-0333P 2.2.5.B]
 - C. Identification of applicable standards and criteria. [DOE/RW-0333P 2.2.5.C]
 - D. Identification and selective application, or development, of appropriate implementing documents. [DOE/RW-0333P 2.2.5.D]
 - E. Identification of field and laboratory testing equipment, or other equipment. [DOE/RW-0333P 2.2.5.E]

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- F. Identification of, or provisions for the identification of, required records and the recording of *objective evidence* (see def.) of the results of the work performed. [DOE/RW-0333P 2.2.5.F]
- G. Identification of quality assurance program verifications of the work performed. [DOE/RW-0333P 2.2.5.G]
- H. Identification of prerequisites, special controls, environmental conditions, processes, or skills. [DOE/RW-0333P 2.2.5.H]
- I. Identification of computer *software* (see def.). [DOE/RW-0333P 2.2.5.I]

4.2.5 Readiness Reviews

- 4.2.5.1 The need for readiness reviews shall be identified by affected organization management for major scheduled or planned work to ensure program objectives are met. [DOE/RW-0333P 2.2.8.1s]
- 4.2.5.2 Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that [DOE/RW-0333P 2.2.8.2s]:
 - A. Work prerequisites have been satisfied. [DOE/RW-0333P 2.2.8.A]
 - B. Personnel have been suitably trained and qualified. [DOE/RW-0333P 2.2.8.B]
 - C. Detailed implementing documents and management controls are available and approved. [DOE/RW-0333P 2.2.8.C]

4.2.6 Peer Reviews

- 4.2.6.1 *Peer* (see def.) reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices. [DOE/RW-0333P 2.2.9.A.1p]

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4.2.6.2 The following conditions are situations for which a peer review shall be considered [DOE/RW-0333P 2.2.9.A.2p]:

- A. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
[DOE/RW-0333P 2.2.9.A.1]
- B. Decisions or interpretations having significant impact on *performance* (see def.) assessment results will be made.
[DOE/RW-0333P 2.2.9.A.2]
- C. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses will be utilized.
[DOE/RW-0333P 2.2.9.A.3]
- D. Detailed technical criteria or standard industry procedures are not available. [DOE/RW-0333P 2.2.9.A.4]
- E. Results of tests are not reproducible or repeatable.
[DOE/RW-0333P 2.2.9.A.5]
- F. Data or interpretations are ambiguous.
[DOE/RW-0333P 2.2.9.A.6]
- G. Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established quality assurance program.). [DOE/RW-0333P 2.2.9.A.7]

4.2.6.3 Management shall determine the need for and, as appropriate, shall initiate peer reviews when the adequacy of a critical body of information can be established by alternate means, but there is significant disagreement regarding the applicability or appropriateness of the alternate means. [DOE/RW-0333P 2.2.9.B]

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- 4.2.6.4 In conducting a peer review, management shall ensure that the [DOE/RW-0333P 2.2.9.C]:
- A. Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to program objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing view points are strongly held within the applicable technical and scientific community concerning issues under review. [DOE/RW-0333P 2.2.9.C.1]
 - B. Collective technical expertise and qualifications of the peer reviewers span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought. [DOE/RW-0333P 2.2.9.C.2]
 - C. Technical areas central to the work to be reviewed receive appropriate proportional representation among the peer reviewers. [DOE/RW-0333P 2.2.9.C.3]
 - D. Potential for technical or organizational partiality is minimized. [DOE/RW-0333P 2.2.9.C.4]
 - E. Peer review group chair person is identified. [DOE/RW-0333P 2.2.9.C.5]
- 4.2.6.5 Peer reviews shall be performed by individuals that have [DOE/RW-0333P 2.2.9.D]:
- A. Technical qualifications in the review area at least equivalent to that needed for the work under review. [DOE/RW-0333P 2.2.9.D.1]
 - B. Technical credentials that are recognized and verifiable. [DOE/RW-0333P 2.2.9.D.2]

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- C. Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or advisor in the work under review and is, to the extent practical, free from any funding considerations. (Note: In those areas where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected shall be documented in the peer review report). [DOE/RW-0333P 2.2.9.D.3]
- D. Initiation of the peer review shall require the development of a planning document that [DOE/RW-0333P 2.2.9.E]:
1. Specifies the work to be reviewed
[DOE/RW-0333P 2.2.9.E.1]
 2. Identifies the size and spectrum of the peer review group [DOE/RW-0333P 2.2.9.E.2]
 3. Describes the expected method and reporting schedule [DOE/RW-0333P 2.2.9.E.3]
 4. Establishes review criteria that shall include, as appropriate [DOE/RW-0333P 2.2.9.E.4]:
 - a. validity of the assumptions
[DOE/RW-0333P 2.2.9.E.4.a]
 - b. alternate interpretations
[DOE/RW-0333P 2.2.9.E.4.b]
 - c. adequacy of requirements
[DOE/RW-0333P 2.2.9.E.4.c]
 - d. appropriateness and limitations of the methods and implementing documents used to complete the work under review
[DOE/RW-0333P 2.2.9.E.4.d]
 - e. adequacy of application
[DOE/RW-0333P 2.2.9.E.4.e]
 - f. accuracy of calculations
[DOE/RW-0333P 2.2.9.E.4.f]

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- g. validity of conclusions
[DOE/RW-0333P 2.2.9.E.4.g]
- h. uncertainty of results and impact if wrong.
[DOE/RW-0333P 2.2.9.E.4.h]

4.2.6.6 The peer review chair person shall provide a peer review that
[DOE/RW-0333P 2.2.9.F]:

- A. Is assigned by each peer reviewer or contains information detailing which peer reviewers have chosen not to sign and why. [DOE/RW-0333P 2.2.9.F.1]
- B. States the work or issue that was reviewed and the conclusions of the review. [DOE/RW-0333P 2.2.9.F.2]
- C. Includes individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate. [DOE/RW-0333P 2.2.9.F.3]
- D. Includes a listing of the peer reviewers and a statement that the qualifications and experience of each reviewer have been evaluated and are acceptable. [DOE/RW-0333P 2.2.9.F.4]

4.2.7 Document Review

- 4.2.7.1 Implementing documents and documents that specify technical or quality requirements shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of the QARD. [DOE/RW-0333P 2.2.10]
- 4.2.7.2 Review criteria shall be established before performing the review. [DOE/RW-0333P 2.2.10.A.1s]
- 4.2.7.3 The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. [DOE/RW-0333P 2.2.10.A.2s]
- 4.2.7.4 Pertinent background information or data shall be made available to the reviewers by the organization requesting the review if the information is not already available to the reviewer. [DOE/RW-0333P 2.2.10.B]
- 4.2.7.5 The review shall be performed by individuals other than the preparer. [DOE/RW-0333P 2.2.10.C]

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- 4.2.7.6 Reviewers shall be technically competent for the subject area of the document being reviewed. *[DOE/RW-0333P 2.2.10.D]*
- 4.2.7.7 The scope of the review shall consider all aspects of the document. *[DOE/RW-0333P 2.2.10.E]*
- 4.2.7.8 Each organization or technical discipline affected by the document shall review the document according to the established review criteria. *[DOE/RW-0333P 2.2.10.E.1.1s]*
- 4.2.7.9 Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change. *[DOE/RW-0333P 2.2.10.E.1.2s]*
- 4.2.7.10 The quality assurance organization shall review implementing documents and changes thereto that translate the QARD into work processes as described in Subsection 4.2.1, Quality Assurance Program Documents, of this PRD. *[DOE/RW-0333P 2.2.10.E.2.1s]*
- 4.2.7.11 The quality assurance organization shall also review changes to other documents if they were required to review the previous version, unless the quality assurance organization has concurred that its review is no longer required. *[DOE/RW-0333P 2.2.10.E.2.2s]*
- 4.2.7.12 Mandatory comments resulting from the review shall be documented and resolved before approving the document. *[DOE/RW-0333P 2.2.10.F]*

4.2.8 Personnel Qualification

- 4.2.8.1 See PRD-5072, 2.2 Personnel Training and Qualification.

4.2.9 Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing

- 4.2.9.1 4.2.9.1 Personnel who perform inspection, nondestructive examination, testing, and auditing shall be qualified in accordance with the requirements of the applicable QARD section covering the activity and PRD 5072, 2.2 Personnel Training and Qualification. *[DOE/RW-0333P 2.2.13]*

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5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

*acceptance**acceptance criteria**activities affecting quality**affected organization**approval**audit**auditor**calibration**certification**cognizant quality engineer**conditions adverse to quality**corrective action**data**external organization**graded approach**guidance**hold point**indoctrination**inspector**issues**item**lead auditor*

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*line organization**management assessment**nonconformance**objective evidence**Office of Civilian Radioactive Waste Management**peer**performance**Price Anderson Amendments Act of 1988**procedure**process**procurement document**Q-list**qualification (personnel)**quality assurance**quality assurance record**Quality Assurance Requirements and Description (QARD)**quality level**repair**safety class, safety significant, low safety consequence, consumer grade**site characterization**software**stop work order**structure, system, and component**supplier**surveillance*

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*suspect/counterfeit item**technical support organization**testing**training**unreviewed safety question**verification**witness point***6. REFERENCES**

10 CFR 21, Reporting of Defects and Noncompliance

10 CFR 820, Procedural Rules for DOE Nuclear Activities

ANSI/ISO 14001-1996, Environmental Management Systems-Specification With Guidance For Use

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE-ID Order 414.A, Quality Assurance, May 2000

DOE O 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, March 1998

DOE Order 414.1A, Quality Assurance, September 1999

DOE/RW-0333P, Quality Assurance Requirements and Description for Civilian Radioactive Waste Management Program, Revision 10

EPA QA/R-5, EPA Requirements for Quality Assurance Projects, 1999

EPA Quality Assurance Management Staff (QAMS)-Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, December 1980

7. APPENDICES

Appendix A, 2.1 Basis

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Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 1	300 1s	4.1.1.21	CR
NQA-1-1997, Requirement 1	300.2s	4.1.1.22	CR
NQA-1-1997, Requirement 2	100(a) 1s and 100(a) 2s	4.1.1.1	CR
NQA-1-1997, Requirement 2	100(a) 3s	4.1.1.15	CR
NQA-1-1997, Requirement 2	100(a) 4s	4.1.1.10	CR
NQA-1-1997, Requirement 2	100(a) 5s	4.1.1.7	CR
NQA-1-1997, Requirement 2	100 (a) 6s	4.1.3.1	CR
NQA-1-1997, Requirement 2	100 (a) 7s	4.1.3.2	CR
NQA-1-1997, Requirement 2	100 (a) 8s	4.1.3.3	CR
NQA-1-1997, Requirement 2	100(a) 9s	4.1.1.20	CR
Company Imposed Requirement	N/A	4.1.1.17	Company Imposed Requirement (CIR)
Company Imposed Requirement	N/A	4.1.1.25	CIR
Company Imposed Requirement	N/A	4.1.1.26	CIR
DOE-ID Order 414.A, Quality Assurance, Attachment 2	3.a.(1) and 3.a.(3)	4.1.1.2	CR
DOE-ID Order 414.A, Attachment 2	3.a.(2).1s	4.1.1.1	CR
DOE-ID Order 414.A, Attachment 2	3.a.(2) 2s	4.1.1.3	CR
DOE-ID Order 414.A, Attachment 2	3.b	4.1.1.8	CR
DOE-ID Order 414.A, Attachment 2	3.c	4.1.1.18	CR
DOE Order 414.1A, Quality Assurance	7.b	4.1.2.1.K	CR
DOE Order 414.1A, Attachment 1	1.a.(3)(b) and 1.a.(3)(c)	4.1.1.16	CR
DOE Order 414.1A, Attachment 1	1.a.(3)(e)	4.1.1.14	CR
DOE Order 414.1A, Attachment 1	1.a.(4)	4.1.1.4	CR
DOE Order 414.1A, Attachment 1	1.a.(5) and 1.a.(3)(f)	4.1.1.9	CR
DOE Order 414.1A, Attachment 1	1.a.(7), 1.b, 1.b.(1) and 1.b.(2)	4.1.1.24	CR
DOE Order 414.1A, Attachment 1	1.a.2	4.1.1.13	CR
DOE Order 414.1A, Attachment 1	1.c.(1)	4.1.1.5	CR
DOE Order 414.1A, Attachment 1	1.c.(2)	4.1.1.6	CR
DOE Order 414.1A, Attachment 1	1.d	4.1.1.23	CR
DOE Order 414.1A, Attachment 1	1a.(3)(d)	4.1.1.2	CR

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DOE Order 440.1A, “Worker Protection Management for DOE Federal and Contractor Employees”, Att. 2	22	4.1.1.12	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description , Revision 10	2.2.1.A	4.2.1.1	Specific Requirement (SR)
DOE/RW-0333P	2.2.1.B	4.1.1.19	CR
DOE/RW-0333P	2.2.1.B.1	4.2.1.2.A	SR
DOE/RW-0333P	2.2.1.B.2	4.2.1.2.B	SR
DOE/RW-0333P	2.2.1.B.2s	4.2.1.2	SR
DOE/RW-0333P	2.2.1.B.3	4.1.1.21	CR
DOE/RW-0333P	2.2.1.B.3	4.1.1.22	CR
DOE/RW-0333P	2.2.1.B.4	4.2.1.2.C	SR
DOE/RW-0333P	2.2.1.C	4.2.1.2.D	SR
DOE/RW-0333P	2.2.1.C.1	4.2.1.2.E	SR
DOE/RW-0333P	2.2.1.C.1.a	4.2.1.2.E.1	SR
DOE/RW-0333P	2.2.1.C.1.b	4.2.1.2.E.2	SR
DOE/RW-0333P	2.2.1.C.1.c	4.2.1.2.E.3	SR
DOE/RW-0333P	2.2.1.C.2	4.2.1.3	SR
DOE/RW-0333P	2.2.1.C.3	4.2.1.4	SR
DOE/RW-0333P	2.2.1.C.4	4.2.1.5	SR
DOE/RW-0333P	2.2.2.A	4.2.2.1	SR
DOE/RW-0333P	2.2.2.A.1	4.2.2.1.A	SR
DOE/RW-0333P	2.2.2.A.2	4.2.2.1.B	SR
DOE/RW-0333P	2.2.2.A.3	4.2.2.1.C	SR
DOE/RW-0333P	2.2.2.A.4	4.2.2.1.D	SR
DOE/RW-0333P	2.2.2.A.5	4.2.2.1.E	SR
DOE/RW-0333P	2.2.2.A.6	4.2.2.1.F	SR
DOE/RW-0333P	2.2.2.B	4.2.2.1.G	SR
DOE/RW-0333P	2.2.3.A	4.2.3.1	SR
DOE/RW-0333P	2.2.3.A Note	4.2.3.1 Note	SR
DOE/RW-0333P	2.2.3.B	4.2.3.2	SR
DOE/RW-0333P	2.2.3.C	4.2.3.3	SR
DOE/RW-0333P	2.2.3.D	4.2.3.4	SR
DOE/RW-0333P	2.2.3.E	4.2.3.5	SR
DOE/RW-0333P	2.2.4	4.1.2.1	CR

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Source	Citation	Requirement	Comments
DOE/RW-0333P	2.2.4.A	4.1.2.1.A	CR
DOE/RW-0333P	2.2.4.B	4.1.2.1.B	CR
DOE/RW-0333P	2.2.4.C	4.1.2.1.C	CR
DOE/RW-0333P	2.2.4.D	4.1.2.1.D	CR
DOE/RW-0333P	2.2.4.E	4.1.2.1.E	CR
DOE/RW-0333P	2.2.4.F	4.1.2.1.F	CR
DOE/RW-0333P	2.2.4.G	4.1.2.1.G	CR
DOE/RW-0333P	2.2.4.H	4.1.2.1.H	CR
DOE/RW-0333P	2.2.4.I	4.1.2.1.I	CR
DOE/RW-0333P	2.2.4.J	4.1.2.1.J	CR
DOE/RW-0333P	2.2.5.1s	4.1.3.1	CR
DOE/RW-0333P	2.2.5.2s	4.2.4.1	SR
DOE/RW-0333P	2.2.5.A	4.2.4.1A	SR
DOE/RW-0333P	2.2.5.B	4.2.4.1.B	SR
DOE/RW-0333P	2.2.5.C	4.2.4.1.C	SR
DOE/RW-0333P	2.2.5.D	4.2.4.1.D	SR
DOE/RW-0333P	2.2.5.E	4.2.4.1.E	SR
DOE/RW-0333P	2.2.5.F	4.2.4.1.F	SR
DOE/RW-0333P	2.2.5.G	4.2.4.1.G	SR
DOE/RW-0333P	2.2.5.H	4.2.4.1.H	SR
DOE/RW-0333P	2.2.5.I	4.2.4.1.I	SR
DOE/RW-0333P	2.2.8.1s	4.2.5.1	SR
DOE/RW-0333P	2.2.8.2s	4.2.5.2	SR
DOE/RW-0333P	2.2.8.A	4.2.5.2.A	SR
DOE/RW-0333P	2.2.8.B	4.2.5.2.B	SR
DOE/RW-0333P	2.2.8.C	4.2.5.2.C	SR
DOE/RW-0333P	2.2.9.A.1	4.2.6.2.A	SR
DOE/RW-0333P	2.2.9.A.1p	4.2.6.1	SR
DOE/RW-0333P	2.2.9.A.2p	4.2.6.2	SR
DOE/RW-0333P	2.2.9.A.2	4.2.6.2.B	SR
DOE/RW-0333P	2.2.9.A.3	4.2.6.2.C	SR
DOE/RW-0333P	2.2.9.A.4	4.2.6.2.D	SR
DOE/RW-0333P	2.2.9.A.5	4.2.6.2.E	SR
DOE/RW-0333P	2.2.9.A.6	4.2.6.2.F	SR
DOE/RW-0333P	2.2.9.A.7	4.2.6.2.G	SR

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DOE/RW-0333P	2.2.9.B	4.2.6.3	SR
DOE/RW-0333P	2.2.9.C	4.2.6.4	SR
DOE/RW-0333P	2.2.9.C.1	4.2.6.4.A	SR
DOE/RW-0333P	2.2.9.C.2	4.2.6.4.B	SR
DOE/RW-0333P	2.2.9.C.3	4.2.6.4.C	SR
DOE/RW-0333P	2.2.9.C.4	4.2.6.4.D	SR
DOE/RW-0333P	2.2.9.C.5	4.2.6.4.E	SR
DOE/RW-0333P	2.2.9.D	4.2.6.5	SR
DOE/RW-0333P	2.2.9.D.1	4.2.6.5.A	SR
DOE/RW-0333P	2.2.9.D.2	4.2.6.5.B	SR
DOE/RW-0333P	2.2.9.D.3	4.2.6.5.C	SR
DOE/RW-0333P	2.2.9.E	4.2.6.5.D	SR
DOE/RW-0333P	2.2.9.E.1	4.2.6.5.D.1	SR
DOE/RW-0333P	2.2.9.E.2	4.2.6.5.D.2	SR
DOE/RW-0333P	2.2.9.E.3	4.2.6.5.D.3	SR
DOE/RW-0333P	2.2.9.E.4	4.2.6.5.D.4	SR
DOE/RW-0333P	2.2.9.E.4.a	4.2.6.5.D.4.a	SR
DOE/RW-0333P	2.2.9.E.4.b	4.2.6.5.D.4.b	SR
DOE/RW-0333P	2.2.9.E.4.c	4.2.6.5.D.4.c	SR
DOE/RW-0333P	2.2.9.E.4.d	4.2.6.5.D.4.d	SR
DOE/RW-0333P	2.2.9.E.4.e	4.2.6.5.D.4.e	SR
DOE/RW-0333P	2.2.9.E.4.f	4.2.6.5.D.4.f	SR
DOE/RW-0333P	2.2.9.E.4.g	4.2.6.5.D.4.g	SR
DOE/RW-0333P	2.2.9.E.4.h	4.2.6.5.D.4.h	SR
DOE/RW-0333P	2.2.9.F	4.2.6.6	SR
DOE/RW-0333P	2.2.9.F.1	4.2.6.6.A	SR
DOE/RW-0333P	2.2.9.F.2	4.2.6.6.B	SR
DOE/RW-0333P	2.2.9.F.3	4.2.6.6.C	SR
DOE/RW-0333P	2.2.9.F.4	4.2.6.6.D	SR
DOE/RW-0333P	2.2.10	4.2.7.1	SR
DOE/RW-0333P	2.2.10.A.1s	4.2.7.2	SR
DOE/RW-0333P	2.2.10.A.2s	4.2.7.3	SR
DOE/RW-0333P	2.2.10.B	4.2.7.4	SR
DOE/RW-0333P	2.2.10.C	4.2.7.5	SR
DOE/RW-0333P	2.2.10.D	4.2.7.6	SR

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Source	Citation	Requirement	Comments
DOE/RW-0333P	2.2.10.E	4.2.7.7	SR
DOE/RW-0333P	2.2.10.E.1.1s	4.2.7.8	SR
DOE/RW-0333P	2.2.10.E.1.2s	4.2.7.9	SR
DOE/RW-0333P	2.2.10.E.2.1s	4.2.7.10	SR
DOE/RW-0333P	2.2.10.E.2.2s	4.2.7.11	SR
DOE/RW-0333P	2.2.10.F	4.2.7.12	SR
DOE/RW-0333P	2.2.11.1s	4.1.5.1	CR
DOE/RW-0333P	2.2.11.2s	4.1.5.2	CR
DOE/RW-0333P	2.2.13	4.2.9	SR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.6.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements